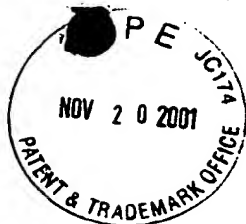


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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
Keiko HASEBE, et al. : EXAMINER: WELLS  
SERIAL NO.: 09/468,777 : GROUP ART UNIT: 1619  
FILED: DECEMBER 21, 1999 :  
FOR: AMPHIPATIC LIPID :  
DISPERSION :

PRELIMINARY RESPONSE AND REQUEST FOR RECONSIDERATION

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

In advance of prosecution, reconsideration of the above-identified application is respectfully requested in view of the following remarks:

REQUEST FOR RECONSIDERATION

Claims 11-19 remain active in this application

The present invention is directed to a dispersion comprising particles of an amphipathic lipid dispersed in a surfactant and aqueous medium.

Amphipathic lipids such as ceramide are reported as components in hair and skin compositions. Formulations of such materials in an amount greater than 2 wt.% can be difficult due to the melting temperature of these materials. Attempts to address this problem by dissolving the ceramide and then emulsification have produced diminished effects.

Accordingly, compositions containing an amphipathic lipid at higher concentrations are sought.

The present invention addresses the problem by providing a dispersion of particles of an amphipathic lipid dispersed in a surfactant and aqueous medium in which the amphipathic lipid has an average particle size of from 0.5 to 150  $\mu\text{m}$ . Applicants have discovered that particles of an amphipathic lipid may be dispersed in a surfactant and aqueous medium providing for increased concentrations of lipid while retaining the desirable effects and that such a formulation provides for reduced surfactant retention on the skin. Such a dispersion of particles is nowhere disclosed or suggested in the prior art of record.

As evidence of the improved reduction of surfactant retention on the skin, Applicants enclose herewith the declaration of Mr. Keiko Hasebe a named inventor of the above-identified application. The data measures the surfactant retention on the skin, for a cleansing system which contains an amphipathic lipid dispersion as claimed, as compared with a cleansing system containing a solid lipid dispersion or no dispersion. For the examiner's convenience a portion of the data is reproduced below:

The results are shown in Table 3.

Table 3

	Amount of lauryl ether acetate salt in <i>stratum corneum</i> ( $\mu\text{g}/\text{cm}^2$ -skin)		
	Systemic cleansing agent		
	A (Blank)	B (Present product)	C (Comparative product)
Average adsorption amount $\pm$ SD	3.0 $\pm$ 0.9	1.3 $\pm$ 0.5	3.2 $\pm$ 0.5

From the results in Table 3, it is apparent that the present product significantly reduces adsorption of the surfactant on the skin whereas comparative product C without any amphipathic lipid does not exhibit such effect although it contains a solid lipid having a particle size similar to that of the amphipathic lipid contained in the present product. Such a result is nowhere disclosed or suggested in the cited prior art of record.

The rejection of Claims 11-19 under 35 U.S.C. §103(a) over Pillai et al, U.S. 5,476,661 in view of Vanlerberghe et al, U.S. 5,985,255 is respectfully traversed.

A composition in which particles of amphipathic lipid are dispersed in a surfactant and aqueous medium is nowhere disclosed or suggested in the cited prior art.

Pillai et al reports a composition comprising 25-hydroxycholecalciferol, a lipid and a vehicle for the hydroxycholecalciferol and lipid. The reference does not describe the lipid component as a dispersion in surfactant and aqueous medium nor an average particle size of 0.5 to 150  $\mu\text{m}$ . Quite simply there is no disclosure in the reference whatsoever of the physical state of the lipid in the composition and accordingly, there is certainly no description of particle size of the lipid. Moreover, there can be no suggestion of a dispersion of particles in a surfactant and aqueous medium, since there is no disclosure of particle whatsoever. Moreover, in Examples 4 and 6-11, the concentration of ceramide never exceeds 1.5 wt.%, consistent with Applicants' description on page 2, line 17 of the specification of the difficulties in formulating such compositions at high concentration of amphipathic lipid.

In contrast, the present invention is directed to a dispersion of amphipathic lipid particles dispersed in surfactant and an aqueous medium in which the average particle size of the lipid is from 0.5 to 150  $\mu\text{m}$ . Applicants note that the claims recite that the amphipathic lipid is dispersed in the surfactant and aqueous medium. The claim limitation of "a

dispersion" is a claim limitation which is not found in the cited reference and accordingly there claimed invention is not obvious over this reference.

Vanlerberghe et al is directed to wax microemulsions in a liquid vehicle, have a particle size of less than 0.5  $\mu\text{m}$  (column 2, lines 21-26).

A general teaching of perfume particle vehicles is found at column 1, lines 11-15, in which wax particles of between 0.1 to 200  $\mu\text{m}$  are described as a vehicle for perfume. This reference teaches, that for a perfume vehicle, wax particles of between 0.1 to 200  $\mu\text{m}$  are used. Accordingly the motivation provided by this reference to include wax particles of a size of from 0.1 to 200  $\mu\text{m}$  is to serve as a perfume vehicle. The reference is silent as to the particle size of from 0.1 to 200  $\mu\text{m}$ , of any components in a composition other than as a perfume vehicle. There is no motivation provided by this reference to formulate all components of a composition to a particle size of from 0.1 to 200  $\mu\text{m}$ . Quite to the contrary, the reference only teaches that, when formulating a composition containing a perfume, that wax particle of a size of from 0.1 to 200  $\mu\text{m}$  are useful as a vehicle for perfume.

Accordingly, the portion of Vanlerberghe et al relied upon by the examiner, teaches only a perfume vehicle of a particle size of from 0.1 to 200  $\mu\text{m}$ . Since the ceramide component of Pillai et al is not a perfume vehicle, there is no motivation to formulate the ceramide component to a particle size of from 0.1 to 200  $\mu\text{m}$ , much less the claimed particle size range of from 0.5 to 150  $\mu\text{m}$ . The simple recitation of a particle size of from 0.1 to 200  $\mu\text{m}$  for a perfume vehicle, in a reference which also describes a hair lotion does not provide motivation to formulate all components of the hair lotion to a particle size of from 0.1 to 200  $\mu\text{m}$ .

Regarding the more specific teachings of the reference and the formulation of a hair lotion (column 2, line 6) the reference only describes a composition of a "microdispersion" in

which the particle size is less than 0.5  $\mu\text{m}$ . There is no suggestion provided by this reference to formulate any component of a hair lotion to a particle size of from 0.5 to 150  $\mu\text{m}$ . The reference only suggest formulation of a hair lotion comprising wax microdispersions of a particle size of less than 0.5  $\mu\text{m}$ .


Since the secondary reference does not provide motivation to formulate all components of a hair lotion to a particle size of from 0.1 to 200  $\mu\text{m}$ , the prior art relied upon by the examiner fails to disclose or suggest the claimed invention in which particles of from 0.5 to 150  $\mu\text{m}$  are dispersed in a surfactant and an aqueous medium. This is a claim limitation which is not suggested by the cited references. Accordingly the claimed invention is clearly not obvious over the cited combination of references and accordingly withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Finally, Applicants respectfully request consideration of the Information Disclosure Statement filed on June 21, 2001. As a Continued Prosecution Application is being filed herewith, consideration of the Information Disclosure Statement filed on June 21, 2001, consideration of which was previously rejected as untimely, is appropriate.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Norman F. Oblon  
Attorney of Record  
Registration No. 24,618

Richard L. Chinn, Ph.D.  
Registration No. 34,305



**22850**

Telephone: (703) 413-3000

Facsimile: (703) 413-2220

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